

JUN 27 2005

PTO/SB/08A (08-03)

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Substitute Infra 149/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 5

Complete if Known

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
Art Unit	1614
Examiner Name	Rebecca Cook

Attorney Docket Number 31140B

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
W		US- 5,798,345	08/25/1998	Knutson et al.	
		US- 5,852,056	12/22/1998	Samid	
		US- 5,716,945	02/10/1998	Grue-Sorensen	
		US- 5,567,695	10/22/1996	Labrie	
		US- 5,565,439	10/15/1996	Piazza et al.	
		US- 5,545,634	08/13/1996	Labrie	
		US- 5,541,172	07/30/1996	Labrie et al.	
		US- 5,532,228	07/02/1996	Neef et al.	
		US- 5,434,146	07/18/1995	Labrie et al.	
		US- 5,362,720	11/08/1994	Labrie	
		US- 5,196,510	03/23/1993	Rodwell et al.	
N		US- 5,115,096	05/19/1992	Shoyab et al.	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
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Examiner Signature

M. Cook

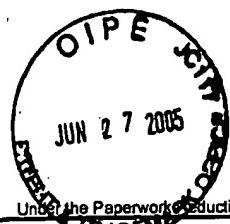
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
Art Unit	1614
Examiner Name	Rebecca Cook
Attorney Docket Number	31140B

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
W		MUSS, H.B., et al., "High-dose progestin therapy for metastatic breast cancer", Annals of Oncology 3:S15-S20 (1992)	
		VOGEL, CHARLES L., "Hormonal Approaches to Breast Cancer Treatment and Prevention: An Overview", Seminars in Oncology, Vol. 23, No. 4 Supp. 9, 2-9 (1996)	
		Locker, G.Y., "Hormonal therapy of breast cancer", Cancer Treatment Reviews 23:221-240 (1998)	
		MUSS, HYMAN B., et al., "Tamoxifen Versus High-Dose Oral Medroxyprogesterone Acetate as Initial Endocrine Therapy for Patients With Metastatic Breast Cancer: A Piedmont	
		(continued from above) "Oncology Associate Study", Journal of Clinical Oncology, Vol. 12 No. 8 (August), (1994)	
		LUNDGREN, S., "Progestins in Breast Cancer Treatment", ACTA ONCOLOGICA, Vo. 31 No. 7 709-722 (1992)	
		VINK-VAN WIJNGAARDEN, T., et al. "Inhibition of Breast Cancer Cell Growth by Combined Treatment with Vitamin D3 Analogues and Tamoxifen" Cancer Research 54:711-717, 11/1/1994	
		CHRISTAKOS, S., "Vitamin D and Breast Cancer", Diet and Breast Cancer, Chapter 12, 115-118 (1994)	
		BEER MD, T. et al., "A Phase I trial of pulse calcitriol in patients with refractory malignancies Pulse dosing permits substantial dose escalation", Cancer Vol. 91, Issue 12	
W		(Continued from above) Pages 2431-2439 (June 15, 2001)	

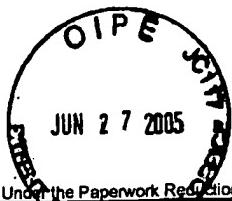
Examiner Signature	<i>Cook</i>	Date Considered	10/27/05
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Substitute for form PTO-892A (07-03) INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/051,662
		Filing Date	January 18, 2002
		First Named Inventor	Gustavo C. Rodriguez
		Art Unit	1614
		Examiner Name	Rebecca Cook
Sheet	3	of	5
		Attorney Docket Number	

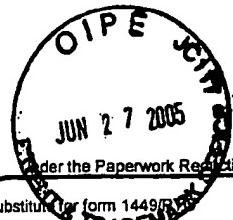
NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
A		GILL, P.G. et al., "Randomized comparison of the effects of tamoxifen, megestrol acetate, or tamoxifen plus megestrol acetate on treatment response and survival in patients		
		(Continued from above) with metastatic breast cancer", Annals of Oncology 7:41-744 (1993)		
		BOWER, M., et al., "Topical calcipotriol treatment in advanced breast cancer", The Lancet, Vol. 337 (March 23, 1991)		
		GULLIFORD, T. et al., "A phase I study of the vitamin D analogue EB 1089 in patients with advanced breast and colorectal cancer", British Journal of Cancer, 6-13, (1998)		
		KANDOUZ, M. et al., "ANTAGONISM BETWEEN ESTRADIOL AND PROGESTIN ON BCL-2 EXPRESSION IN BREAST-CANCER CELLS, Int. J. Cancer: 68, 120-125 (1996)		
		Vogel, C., "Update on the current use of hormonals as therapy in advanced breast cancer", Use of hormonals in advanced breast cancer, Anti-Cancer Drugs, 14:265-273 (2003)		
		BEAT, T., "Anastrozole versus progestin/tamoxifen", European Journal of Cancer 38 Supplement 6, S49-S51 (2002)		
		BURAS, R. et al., "Vitamin D receptors in breast cancer cells", Breast Cancer Research and Treatment 31:191-202, (1994)		
		LOVE-SCHIMENTI, C. et al., "Antiestrogen Potentiation of Antiproliferative Effects of Vitamin D3 Analogs in Breast Cancer Cells 1", Cancer Research 56, 2789-2794 (6/15/96)		
N		Smith, D., et al., "A Phase I Trial of Calcitriol (1,25-Dihydroxycholecalciferol) in Patients with Advanced Malignancy1", Clinical Cancer Research, Vol. 5, 1339-1345, (6/1999)		

Examiner Signature	<i>Rebecca Cook</i>	Date Considered	10/27/05
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Substitute for form 1449 (P-10)

TRADEMARKS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

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of

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Complete If Known

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
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Attorney Docket Number	31140B

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W		SPEROFF MD, L., "The Risk of Breast Cancer Associated with Oral Contraception and Hormone Replacement Therapy", Women's Health, Vol. 2, 63-74, (1992)	
		JAMES, S. et al., "Effects of a new synthetic vitamin D analogue, EB 1089, on the oestrogen-responsive growth of human breast cancer cells", Journal of Endocrinology,	
		(Continued from above) 141, 555-563, (1994)	
		MILLER, W. et al., "Anti-tumor Effects of Letrozole", Cancer Investigation, Vol. 20, Suppl. 2 pp. 15-21, (2002)	
		BLAND MD, K., et al., "Current Status of Endocrine Therapy for Advanced Breast Cancer", Ann Surg. Oncol., Vol. 6, No. 8, 4S-7S, (1999)	
		BEER, T. et al., "Beer Abstract" (2002)	
		Mathiasen, I. et al., "EB 1089, A NOVEL VITAMIN D ANALOGUE, HAS STRONG ANTIPIROLIFERATIVE AND DIFFERENTIATION INDUCING EFFECTS ON CANCER CELLS", J. Steroid Biochem. Molec.	
		(Continued from above) Biol. Vol. 46, No. 3, pp. 365-371, (1993)	
		KAUFMANN, M., "A Review of Endocrine Options for the Treatment of Advanced Breast Cancer", Oncology 1997; 54 (suppl 2):2-5	
W		HOLICK, M., "Evolutionary Biology and Pathology of Vitamin D", 79-83 Symposium Vitamin D, 1990	

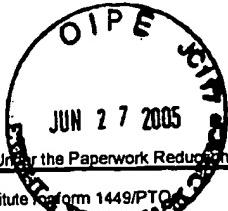
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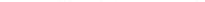
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<p>Substitute Form 1449/PTO-1 TRADEMARK</p>		Application Number	10/051,662
		Filing Date	January 18, 2002
		First Named Inventor	Gustavo C. Rodriguez
		Art Unit	1614
		Examiner Name	Rebecca Cook
Sheet	5	of	5
		Attorney Docket Number 31140B	

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Examiner Signature		Date Considered	10/27/05
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